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Revisions Made at the Suggestion of OMB or in Response to Comments from OMB

REVISIONS MADE IN RESPONSE TO OMB COMMENTS 10-23-03

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1240

Centers for Disease Control and Prevention

42 CFR Part 71

[Docket No. 2003N-0400]

Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals

AGENCIES: Centers for Disease Control and Prevention, Food and Drug Administration (HHS).

ACTION: Interim final rule; opportunity for public comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are issuing this interim final rule to amend their regulations to establish new restrictions and modify existing restrictions on the import, capture, transport, sale, barter, exchange, distribution, and release of African rodents, prairie dogs, and certain other animals. We are taking this action to prevent the spread of monkeypox, a communicable disease, in the United States.

DATES: The interim final rule is effective on [insert date of publication in the FEDERAL REGISTER]. Submit written or electronic comments on this interim final rule by [insert date 75 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: For FDA: Send written comments on the rule and on the information collection to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630

Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

For CDC: Send written comments on the information collection to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Rd., MS E11, Atlanta, GA 30333. Comments on the rule itself should be sent to FDA's Division of Dockets Management (see FDA addresses).

~~The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.~~

FOR FURTHER INFORMATION CONTACT:

For information regarding FDA:

Philip L. Chao,

Office of Policy and Planning (HF-23),

Food and Drug Administration,

5600 Fishers Lane,

Rockville, MD 20857,

301-827-0587.

For information regarding CDC:

James E. Barrow,

National Center for Infectious Diseases,

Centers for Disease Control and Prevention,

Several States have issued orders or emergency rules to prohibit the importation, sale, distribution, release, disposal, and/or display of prairie dogs and certain rodents (Refs. 5 through 11). However, these State efforts are limited to their respective jurisdictions, and some State orders or rules expire on a specific date, while others differ in the types of animals and actions that are covered. Communicable diseases, such as monkeypox, are not confined by State borders ~~or by time~~ and, as shown by the presence of the monkeypox virus in prairie dogs, may affect multiple animal species. Consequently, Federal action was necessary to help prevent the spread of monkeypox. On June 11, 2003, the Director of CDC and the Commissioner of Food and Drugs, under 42 CFR 70.2 and 21 CFR 1240.30 respectively, issued a joint order (Ref. 12) prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of:

- Prairie dogs (Cynomys sp.);
- Tree squirrels (Heliosciurus sp.);
- Rope squirrels (Funisciurus sp.);
- Dormice (Graphiurus sp.);
- Gambian giant pouched rats (Cricetomys sp.);
- Brush-tailed porcupines (Atherurus sp.), and
- Striped mice (Hybomys sp.).

The June 11, 2003, order did not apply to the transport of these animals to veterinarians or animal control officials or other entities under guidance or instructions issued by Federal, State, or local government authorities. In addition, under 42 CFR 71.32(b), CDC implemented an immediate embargo on the importation of all rodents from Africa (order Rodentia).

offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, or release into the environment:

- Prairie dogs (Cynomys sp.),
- African Tree squirrels (Heliosciurus sp.),
- Rope squirrels (Funisciurus sp.),
- African Dormice (Graphiurus sp.),
- Gambian giant pouched rats (Cricetomys sp.),
- Brush-tailed porcupines (Atherurus sp.),
- Striped mice (Hybomys sp.), or
- Any other animal so prohibited by order of the Commissioner of Food and Drugs

because of that animal's potential to transmit the monkeypox virus.

For convenience, this preamble will refer to the above animals as "listed animals."

The interim final rule covers the listed animals because animals from those species have been associated, either directly through laboratory tests or indirectly through epidemiological evidence, in the current outbreak of the monkeypox virus in humans (Ref. 14). In general, the animals identified in 21 CFR 1240.63 are the same as those listed in the CDC-FDA order dated June 11, 2003, except that the rule also refers to other, yet-unspecified kinds of animals that the Commissioner of Food and Drugs may prohibit by order. FDA included the latter "catch-all" provision in § 1240.63 because the agency cannot preclude the possibility that monkeypox may spread to other animal species, and, if monkeypox is found in other animals, FDA needs to be able to list those animals quickly. FDA derives its authority to list such animals by order from section 361 of the Public Health Service Act, which is the same statutory authority under which it is issuing this interim final rule. This statutory provision authorizes the Secretary to make and

would create a serious risk to animal and human health because the monkeypox virus could then spread to domestic animal species and to humans and could become established in the United States. Therefore, if you prevent or attempt to prevent FDA from causing an animal to be quarantined or destroyed, you may be subject to criminal penalties. Penalties are discussed in part IV below.

FDA repeats that prohibiting the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, and release of listed animals is vital to prevent the monkeypox virus from becoming established and spreading in the United States. Nevertheless, the agency also recognizes that there are limited circumstances warranting exemptions from some prohibitions, such as the need to transport an animal for zoological, educational, medical, scientific, or other purposes. Consequently, 21 CFR 1240.63(a)(2) allows you to:

- Transport a listed animal to a veterinarian or animal control official for veterinary care, quarantine, or destruction purposes; and
- Capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and/or release a listed animal into the environment after receiving written permission from FDA. Section 1240.63(a)(2)(ii) states, however, that you may not seek written permission to sell, barter, exchange, or offer to sell, barter, or exchange a listed animal as a pet. We do not intend to permit pet sales (or barter or exchange) because the monkeypox outbreak developed in the pet industry, and exposure to infected animals intended as pets led to infections in prairie dogs. The infected prairie dogs, in turn, infected humans. Thus, pets present a greater potential risk for transmitting the monkeypox virus. compared to animals in the wild

complete the translocation process without an exemption from FDA because the translocation process began when the State was not listed? The Wild-to-Wild document also created the potential for conflicting policies between States. For example, one State could adopt strict criteria to ensure that certain safeguards were observed, while a neighboring State could have no criteria at all and decide on wild-to-wild translocations on an ad hoc basis. Given these issues and potential problems, we have decided that the written permits in 21 CFR 1240.63(a)(2)(ii)(B) must be obtained and will no longer observe the policies expressed in the Wild-to-Wild document. In other words, all wild-to-wild translocations or transportation of prairie dogs, other than those that occurred before the date of this interim final rule, will need a written permit under 21 CFR 1240.63(a)(2)(ii)(B), and the interim final rule supersedes the Wild-to-Wild document.

3. What Actions Can FDA Take? (21 CFR 1240.63(b))

FDA has limited knowledge as to which kinds of animals in the United States may be vulnerable to the monkeypox virus, but it is extremely difficult, if not impossible, to eradicate a virus once it becomes established in a country or region. For example, the West Nile virus was unknown in the United States before 1999. The virus apparently arrived in the eastern United States and quickly spread, via mosquitoes, to domestic bird species, other animal species (such as horses), and to humans. ~~From~~ 1999 ~~to 2001~~, the virus was reported in 4 States; by In October, 2003, ~~more than 20~~ 45 States had reported cases of the West Nile ~~disease, and~~ virus activity in humans or other animals. the virus's continued spread in the United States suggests that it is now permanently established in the United States.

To prevent the monkeypox virus from spreading and becoming established in the United States, 21 CFR 1240.63(b)(1) authorizes FDA to take the following actions:

42 CFR 71.56(a) contains only two general prohibitions. In brief, under 42 CFR 71.56(a)(1)(i), you must not import or offer to import any rodents, whether dead or alive, that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa; any products derived from such rodents, any other animal, whether dead or alive, whose importation the Director of CDC has prohibited by order, or any products derived from such animals. This provision is intended to prevent the further importation of infected and potentially-infected rodents and represents a slight modification from the import restriction that appeared in the June 11, 2003, order. The June 11, 2003, order barred importation of "all rodents from Africa." The rule's import prohibition is intended to make clear that it covers any rodents that were caught in Africa and then shipped directly to the United States or shipped to other countries before being imported to the United States. The prohibition also applies to rodents whose native habitat is in Africa, even if those rodents were born elsewhere. For example, 42 CFR 71.56(a)(1)(i) would apply to a Gambian giant pouched rat even if that animal was born outside Africa. A broad import ban on African rodents is necessary because there is no quick, practical method for determining whether a specific animal was born in a particular geographic region. The import restriction complements efforts taken by the U.S. Fish and Wildlife Service to prevent the importation of infected animals (Ref. 20).

Similarly to 21 CFR 1240.63, 42 CFR 71.56 applies to dead animals. Some individuals have attempted to conceal "bushmeat" (a term used to describe meat obtained from animals taken in the wild or the "bush") from Federal authorities since the June 11, 2003, order was issued and others have attempted to import preserved specimens of listed species. The monkeypox virus can remain infectious in bushmeat (Refs. 1, ~~and~~ 21, and 38), and CDC is unaware of data demonstrating the safety of raw or even prepared bushmeat. Preparation methods such as

inflation). We have conducted analyses of the rule, and have determined that the rule is consistent with the principles set forth in the Executive Order and in these statutes.

The interim final rule is not a significant regulatory action as defined by the Executive Order. This regulatory action is also not a major rule under the Congressional Review Act. However, the Regulatory Flexibility Analysis concludes that the rule may have a significant impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require us to prepare a statement of costs and benefits for the interim final rule because the rule is not expected to result in any one-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is about $110 million.

~~Based on a review of the available data, we believe that the benefits of the rule would justify its costs given the highly infectious nature of monkeypox and the substantial risks it would pose if released into the United States environment.~~

A. Objectives and Basis for the Action

Incomplete data preclude us from developing a quantitative estimate of the economic benefits or costs of this rule. However, we believe that the rule is necessary to minimize the risk of establishing and spreading the monkeypox virus. The rule formalizes an administrative ban on trade, transport, and import of certain animals and sets forth a process to obtain exemptions. In particular, the interim final rule prohibits the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, and release into the environment of prairie dogs and other specific animals, and it prohibits importation of African rodents. The interim final rule supersedes the June 11, 2003, order and allows permits for exemptions in cases that pose little risk of establishing or spreading the monkeypox virus.

B. The Nature of the Impacts

This rule has several impacts. It continues and clarifies the prohibition of the import of African rodents, as well as the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, and release into the environment of prairie dogs and other specific animals, but allows parties to apply for exemptions in instances that would not pose a risk of establishing or spreading the monkeypox virus. Thus, importers of small mammals would have to find animals other than African rodents and other listed animals to satisfy market demands for unusual pets. ~~In addition,~~ firms that supply prairie dogs as pets would be unable to do so and would have to switch to different animals. While we have not generated quantitative estimates of the magnitude of these effects, available evidence suggests that they are relatively small.

In addition, some animals may be destroyed if it is determined that such action is necessary to prevent the further spread of monkeypox in the United States.

We invite comment on the economic analysis in support of this interim final rule.

C. Need for the Rule

A new infectious disease, if uncontrolled, can have large adverse economic effects. It does so because a single infection can lead to a few new cases, which in turn can lead to many others. Through this multiplier effect, a single uncontrolled case of a new disease may trigger an epidemic. For example, West Nile virus, a mosquito-borne zoonotic disease originally from Africa, sickened more than four thousand Americans and killed 284 in 2002 alone, although it was not recorded in the United States before 1999 (Ref. 24). West Nile virus has also affected populations of many indigenous species of birds and mammals. Existing economic incentives to control such risks are generally inadequate because the costs of such risks to third parties are not borne by the owners of infected animals.

Notwithstanding the inadequacy of incentives to control risks associated with monkeypox virus, trade in some of the animal species affected by this rule fell before any announced

offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and release into the environment prairie dogs and other specific animals when it otherwise would be prohibited. Relative to the outright prohibition in the June 11, 2003, order, permits would lower costs to parties seeking to import, capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and release into the environment listed animals. For example, zoos and related animal facilities, prairie dog relocation services, and research labs may request permission to import, capture, transport, or sell listed animals, and, if permission is granted, they may continue such activities that would otherwise be prohibited by the June 11, 2003, order. Generating quantitative estimates of the cost savings from such permits is not possible because of the uncertainty associated with how and when such permits would be granted. While these exemptions may in principle pose some risks, we believe that these are negligible because permits would be granted only in instances where prohibited activities pose no risk of establishing or spreading the monkeypox virus.

E. Alternatives

Sound economic analysis requires an assessment of reasonable alternatives. The key alternative, and one on which we solicit comment, is a "sunset" provision ending the domestic restrictions by January, 2004, unless we made a determination that the ban was necessary to protect health and safety. The economic advantage of this alternative relative to this interim final rule may be the elimination of permitting costs for capturing, transporting, selling, bartering, exchanging, distributing, or releasing an animal that has been only a conduit and not a source of infection, as well as allowing for resumption of a prairie dog market as existed before

disease compatible with the clinical description of monkeypox; however, the rabbit owner was not a laboratory-confirmed case.

veterinary clinic that also had an infected prairie dog became ill and died. The rabbit died spontaneously, but the owner of that rabbit became ill with a ~~characteristic illness~~ (Ref. 28). This rule would reduce the risk of the monkeypox virus spreading among both species known to carry it, as well as the possibility of it spreading through wild and pet species currently not known to carry it.

Because this interim final rule would be expected to reduce the frequency of monkeypox outbreaks, there would also be a commensurate reduction in outbreak traceback efforts by the Federal Government, as well as possible state and local government efforts. The costs of these traceback efforts would vary depending on the size of the outbreak.

G. Costs

The costs of this interim rule are the lost value to consumers and producers associated with not being able to import, capture, transport, sell, barter, exchange, distribute, or release prairie dogs and certain African rodents. We believe that the costs are not likely to be high, because the monkeypox outbreak has already sharply curtailed the trade in prairie dogs, as described above. This curtailment occurred prior to Federal regulatory action. Unfortunately, we lack data on the magnitude of trade that has occurred since the outbreak was publicized in June, and so we present instead data from before the outbreak. These data overstate the costs of the rule insofar as they ignore the reduction in volume of trade likely already to have resulted from the outbreak itself. Indeed, if the data shown in Figure 1 are representative of broader and long-lasting market conditions, then the interim final rule's prohibition has no impact on sales of prairie dogs as pets because trade has vanished as a result of the outbreak. If the trade in prairie dogs would otherwise have resumed in the absence of this order, then costs would occur.

endemic to domestic pets and wildlife and further affect human health. For this reason it was determined to be not acceptable.

A third alternative would have been to exempt small businesses from this interim final rule. However, because about 94 percent of pet stores and probably a large portion of small animal trappers and wholesalers/distributors are small businesses, this option would have compromised the rule's ability to reduce the risk of establishing or spreading the monkeypox virus in the United States.

VII. Paperwork Reduction Act of 1995

This interim final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Both FDA and CDC have requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). Such emergency processing is necessary in order to respond immediately to the monkeypox outbreak. This interim final rule, at 21 CFR 1240.63(a)(2)(ii)(A) and (B) and 42 CFR 71.56(a)(2)(i) and (ii), contains information collection requirements. In compliance with the PRA (44 U.S.C. 3507(d)), we have submitted a copy of the information collection provisions of this interim final rule to OMB for review.

The information collections in this interim final rule have been approved under OMB control number 0910-0519 (for 21 CFR 1240.63) and OMB control number 0920-0615 (for 42

CFR 71.56). An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it contains a currently valid OMB control number.

Title: Control of Communicable Diseases; Requests for Exemptions from the Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals.

Description: Monkeypox is a rare zoonotic viral disease that occurs primarily in the rain forest countries of central and west Africa. Studies have shown that infected rodents are capable of transmitting the monkeypox virus to humans. Limited person-to-person spread of infection has been reported in disease-endemic areas in Africa. It is likely the virus is entering the United States by way of rodent species imported from Africa. Further transmission of the virus ~~can~~ likely occurred in the storage and handling of these rodents during sale and distribution within the United States. This resulted in secondary transmission to domestic prairie dogs in this country housed in the same animal-holding facility or pet shop. Introduction of exotic species, such as African rodents, poses a serious public health threat because of the potential of human monkeypox virus infection. Transport, sale, or any other type of distribution, including release into the environment, of certain species of rodents poses a serious public health threat because of the potential for further spread of the monkeypox virus to other animal species and to humans. To prevent the establishment and spread of the monkeypox virus in the United States, we are prohibiting the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, or release into the environment of prairie dogs and certain rodents and any other animal so prohibited by order of the Commissioner of Food and Drugs. We are also prohibiting the importation of all rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or any other animal whose importation the Director of CDC has prohibited by order. The rule provides for

37. Exotic Pets.com, taken from http://www.exoticpets.com/Show_Ads.asp?petid=16 on June 12, 2003.

38. Hutin, Y.J.F., et al., "Outbreak of Human Monkeypox, Democratic Republic of Congo, 1996-1997," Emerging Infectious Diseases, 7:434-438 (May-June, 2001).

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

42 CFR Part 71

Airports, Animals, Communicable diseases, Harbors, Imports, Pesticides and pests, Public health, Quarantine, Reporting and recordkeeping requirements.

Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs and to the Director, Centers for Disease Control and Prevention, 21 CFR 16 and 1240 and 42 CFR 71 are amended as follows:

21 CFR CHAPTER I

PART 16–REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR Part 16 continues to read as follows:

AUTHORITY: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for § 1240.63(c)(3) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

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§ 1240.63(c)(3), relating to a written order to cause an animal to be placed in quarantine or to cause an animal to be destroyed.

* * * * *

PART 1240–CONTROL OF COMMUNICABLE DISEASES

3. The authority citation for 21 CFR part 1240 continues to read as follows:

AUTHORITY: 42 U.S.C. 216, 243, 264, 271.

4. Section 1240.63 is added to subpart C to read as follows:

§ 1240.63 African rodents and other animals that may carry the monkeypox virus

(a) What Actions Are Prohibited? What Animals Are Affected?

(1) Except as provided in paragraph (a)(2) of this section,

(i) You must not capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, or release into the environment, any of the following animals, whether dead or alive:

(A) Prairie dogs (Cynomys sp.),

(B) African Tree squirrels (Heliosciurus sp.),

(C) Rope squirrels (Funisciurus sp.),

(D) African Dormice (Graphiurus sp.),

(E) Gambian giant pouched rats (Cricetomys sp.),

Pre-Publication Editorial Revisions
made by FDA's Regulations Editorial Section
or by the Office of the Federal Register

37. Exotic Pets.com, taken from http://www.exoticpets.com/Show_Ads.asp?petid=16 on June 12, 2003.

38. Hutin, Y. J. F., et al., "Outbreak of Human Monkeypox, Democratic Republic of Congo, 1996-1997," Emerging Infectious Diseases, 7:434-438 (May through June, 2001).

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

42 CFR Part 71

Airports, Animals, Communicable diseases, Harbors, Imports, Pesticides and pests, Public health, Quarantine, Reporting and recordkeeping requirements.

Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs and to the Director, Centers for Disease Control and Prevention, 21 CFR parts 16 and 1240 and 42 CFR part 71 are amended as follows:

Kent Giles 10-29-03 OFR

21 CFR CHAPTER I

PART 16–REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR Part 16 continues to read as follows:

AUTHORITY: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for

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§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

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K. Giles
10-29-03

§ 1240.63(c)(3), relating to a written order to cause an animal to be placed in quarantine or to cause an animal to be destroyed.

* * * * *

PART 1240–CONTROL OF COMMUNICABLE DISEASES

3. The authority citation for 21 CFR part 1240 continues to read as follows:

Kent Giles
10-29-03
OPR

AUTHORITY: 42 U.S.C. 216, 243, 264, 271.

4. Section 1240.63 is added to subpart D to read as follows:

§ 1240.63 African rodents and other animals that may carry the monkeypox virus

(a) What Actions Are Prohibited? What Animals Are Affected?

(1) Except as provided in paragraph (a)(2) of this section,

(i) You must not capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, or release into the environment, any of the following animals, whether dead or alive:

(A) Prairie dogs (Cynomys sp.),

(B) African Tree squirrels (Helioscirurus sp.),

(C) Rope squirrels (Funisciurus sp.),

(D) African Dormice (Graphiurus sp.),

You may also fax your request to the Division of Compliance (using the same address in the previous sentence ~~paragraph (a)(1)(i)(A)~~ at 301-827-1498. Kent Giles 10-29-04

(B) Your request must state the reasons why you need an exemption, describe the animals involved, describe the number of animals involved, describe how the animals will be transported (including carrying containers or cages, precautions for handlers, types of vehicles used, and other procedures to minimize exposure of animals and precautions to prevent animals from escaping into the environment), describe any holding facilities, quarantine procedures, and/or veterinarian evaluation involved in the animals' movement, and explain why an exemption will not result in the spread of monkeypox within the United States.

(C) We (FDA) will respond, in writing, to all requests, and we also may impose conditions in granting an exemption.

(b) What Actions Can FDA Take?

(1) To prevent the monkeypox virus from spreading and becoming established in the United States, we may, in addition to any other authorities under this part:

(i) Issue an order causing an animal to be placed in quarantine,

(ii) Issue an order causing an animal to be destroyed, or

(iii) Take any other action necessary to prevent the spread of the monkeypox virus.

(2) Any order to cause an animal to be placed in quarantine or to cause an animal to be destroyed will be in writing.

(c) How Do I Appeal an Order?

(1) If you receive a written order to cause an animal to be placed in quarantine or to cause an animal to be destroyed, you may appeal that order. Your appeal must be in writing and

be submitted to the Food and Drug Administration District Director whose office issued the order, and you must submit the appeal within two business days after you receive the order.

(2) As part of your appeal, you may request an informal hearing. Your appeal must include specific facts showing there is a genuine and substantial issue of fact that requires a hearing.

(3) If we grant your request for an informal hearing, we will follow the regulatory hearing requirements at in part 16, except that:

(i) The written order will serve as notice of opportunity for that hearing, for purposes of § 16.22(a) of this chapter;

Kent Giles 10-29-03 OPR

(ii) The presiding officer will issue a decision rather than a report and a recommended decision. The presiding officer's decision constitutes final agency action.

42 CFR CHAPTER I

PART 71–FOREIGN QUARANTINE

5. The authority citation for 42 CFR part 71 continues to read as follows:

AUTHORITY: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243), secs. 361-369, PHS Act, as amended (42 U.S.C. 264-272).

6. Section 71.56 is added to subpart F read as follows:

§ 71.56 African rodents and other animals that may carry the monkeypox virus.

(a) What Actions Are Prohibited? What Animals Are Affected?

(1) Except as provided in paragraphs (a)(2) and (a)(3) of this section,

(i) You must not import or attempt to import any rodents, whether dead or alive, that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, any products

derived from such rodents, any other animal, whether dead or alive, whose importation the Director has prohibited by order, or any products derived from such animals; and

(ii) You must not prevent or attempt to prevent the Centers for Disease Control and Prevention (CDC) from causing an animal to be quarantined, re-exported, or destroyed under a written order.

(2) The prohibitions in paragraph (a)(1) of this section do not apply if you have written permission from CDC to import a rodent that was obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or an animal whose importation the Director has prohibited by order.

(i) To obtain such written permission from CDC, you must send a written request to Division of Global Migration and Quarantine, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333. You may also fax your request to the Division of Global Migration and Quarantine (using the same address in the previous sentence ~~paragraph (a)(2)(i)~~) at 404-498-1633.

(ii) Your request must state the reasons why you need an exemption, describe the animals involved, describe the number of animals involved, describe how the animals will be transported (including carrying containers or cages, precautions for handlers, types of vehicles used, and other procedures to minimize exposure of animals and precautions to prevent animals from escaping into the environment), describe any holding facilities, quarantine procedures, and/or veterinarian evaluation involved in the animals' movement, and explain why an exemption will not result in the spread of monkeypox within the United States. Your request must be limited to scientific, exhibition, or educational purposes.

Kent Giles 10-29-03 OFR

(c) How Do I Appeal an Order?

If you received a written order to quarantine or re-export an animal or to cause an animal to be destroyed, you may appeal that order. Your appeal must be in writing and be submitted to the CDC official whose office issued the order, and you must submit the appeal within 2 business days after you receive the order. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

Dated: OCT -6 2003

Tommy G. Thompson,
Secretary of Heath and Human Services.

[FR Doc. 03-????? Filed ??-??-03; 845 am]

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B. Bodo
10-28-03

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